AR201-13797

Jessica Sandler <jessicas@peta.org> on 06/05/2002 05:09:23 PM

To: NCIC OPPT/DC/USEPA/US@EPA, ChemRTK HPV/DC/USEPA/US@EPA, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, LUANN_MALONEY@fmc.com

cc:

Subject: Pubic comments on FMC test plan

Attached please find the comments of the U.S. animal protection community.

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HPV test plan comments -- FMC.pdf

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June 5, 2002

Christine Todd Whitman, Administrator
U. S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N. W.
Washington, DC 20460

Subject: Comments on the FMC's Cyclopropanecarboxylic acid, 3(2,2,-dichloroethenyl)-2,2-dimethyl-, methyl ester and Methylallyloxyphenol test plans.

Dear Administrator Whitman:

The following comments on FMC's test plans for the above-named closed system intermediates are submitted on behalf of People for the Ethical Treatment of Animals (PETA), the Physicians Committee for Responsible Medicine (PCRM), the Humane Society of the United States, the Doris Day Animal League and Earth Island Institute. These health, animal protection and environmental organizations have a combined membership of more than ten million Americans.

FMC has developed two test plans for closed system intermediates and is proposing to conduct developmental toxicity tests for these two compounds. These tests will kill more than 2,000 animals.

We appreciate the fact that FMC has provided clear documentation that these compounds are closed-system intermediates and intends to postpone its proposed testing per the October 1999 agreement among the EPA, industry and health, animal protection and environmental organizations. However, the test plan still violates the following sections of that agreement:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.

7. Participants shall not develop sub-chronic or reproductive toxicity data for the HPV chemicals that are solely closed system intermediates, as defined by the OECD/SIDS guidelines.

FMC has presented a test plan that is inadequate in terms of providing a "*thoughtful, qualitative analysis*" of the toxicity of these compounds. No

discussion is provided on the toxicity of the compounds, the toxicity of similar compounds or products of the processes, nor is the description of the process interpretable by someone not already intimately familiar with it. FMC has not considered the toxicity of similar compounds and has not maximized the use of any existing related data. We once again ask that the EPA act on its existing guidance to discourage rote checklist-based test plans.

As far as we are able to ascertain from its test plans, FMC does not provide the specific test guideline it intends to use to conduct the developmental toxicity tests. We assume it intends to use OECD guideline 414, but FMC does not specify whether it will use rabbits (approximately 900 animals per test) or rats (as many as 1,300 animals per test) or both. This information should be provided. In addition, OECD test guideline 414 calls for dosing pregnant animals over the course of 6 to 18 days. For the same reasons that it is inappropriate to conduct sub-chronic and reproductive toxicity tests for closed-system intermediates, it is surely equally inappropriate to conduct this repeat-dose developmental toxicity testing. In the interests of reducing the number of tests conducted, the OECD SIDS manual (Chapter 3: "Data evaluation, preparation of SIDS dossiers and testing plans") excludes subchronic testing from substances to which the only exposure may be accidental and an isolated incident. It further states that "in view of their limited exposure potential, intermediates should have a lower priority in the context of the SIDS work and, consequently, the choice of these chemicals by Sponsor countries is discouraged." By proposing to conduct developmental toxicity testing, FMC is essentially developing sub-chronic data on the toxicity of these closed-system intermediates and, at the same time, condemning thousands of animals to a painful death.

In summary, FMC should revisit these test plans, provide a qualitative analysis of existing toxicological information, review the toxicity of a broader range of similar compounds that would provide greater insight into the overall hazard of these chemicals, and remove the proposed developmental toxicity testing from its test plans.

Thank you for the opportunity to comment. If you have any questions, please contact me at 757-622-7382, ext.1304 or via e-mail at jessicas@peta.org.

Sincerely,

Jessica Sandler, MHS
Federal Agency Liaison